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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/097,791	06/16/1998	MICHAEL T. BOYCE-JACINO	13065	3332

7590

06/24/2003

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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

33

DATE MAILED: 06/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/097,791

Applicant(s)
Boyce-Jacino et al.

Examiner
Ardin Marschel

Art Unit
1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/4/02 and 3/24/03
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-20, 23-31, and 33-36 is/are pending in the application.
- 4a) Of the above, claim(s) 29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-20, 23-28, 31, and 33-36 is/are rejected.
- 7) ☒ Claim(s) 1-3, 21, 22, and 32 have been canceled. ~~_____~~
- 8) ☒ Claims 4-20, 23-31, and 33-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

Applicants' arguments, filed 11/4/02 and 3/24/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

RESTRICTION REQUIREMENT

Applicants REMARKS, filed 3/24/03, discussed the restriction requirement regarding claims 4-20 and 23-34. Applicants are firstly reminded that a restriction requirement, mailed 7/7/99, was responded to by applicants in Paper No. 8, filed 1/13/00, to elect methods for analyzing a sequence (Group I) which correspond to presently pending claims 4-20, 23-28, 31, and 33-36. Claims 29 and 30 remain pending in the instant application and remain withdrawn from consideration as being directed to non-elected Group II directed to sequence arrays. Therefore, contrary to the allegation of applicants a restriction requirement has been previously set forth as well as Group I being elected by applicants. The restriction requirement was made FINAL in the Office action, mailed 3/21/00, as Paper No. 10. Applicants then allege that all claims depend directly or indirectly from claim 4. This allegation is not correct for claims 29 and 30 which do not depend from claim 4 and are still pending, however, withdrawn

from consideration as discussed above.

NEW MATTER

Claims 4-20, 23-28, 31, and 33-36 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 4 has been amended to require that captured template must not contain a region that is capable of forming a duplex with the spacer region which is adjacent to the complementarity to the primer region of the sequencing reagent. Figure 2 and pages 15-16 of the specification has been pointed to for support for this amendment. Consideration of Figure 2 and said pages has failed to reveal any spacial limitation as to spacer complementarity as compared to primer complementarity regions such to support the "not adjacent" limitation in part (c) of amended claim 4 regarding spacer capability of forming a duplex. It is acknowledged that the spacer region as depicted in Figure 2 does not form a duplex adjacent to the primer region duplex, but that this depiction and related discussion lacks any written basis for the present claim limitation which defines a spacer duplex forming capability or not whether adjacent to the primer duplex region or not. This limitation regarding spacer and

primer complementarity regions is therefore NEW MATTER due to lacking written description as filed. Claims dependent from claim 4 directly or indirectly also contain this NEW MATTER due to said dependence. This rejection is maintained from the previous office action, mailed 7/16/02, and as necessitated by amendment regarding claims which have been amended to depend from claim 4 as well as newly added claims 35 and 36 which also depend from claim 4

Support for new claim 31 has been pointed to by applicants on page 29 of the specification regarding mass spectroscopy detection of mass change. Consideration of said page 29 citation reveals that only a particular mass spectroscopy is therein cited which is MALDI-TOF mass spectroscopy. No broader or generic mass spectroscopy as now in claim 31 has written basis. This broadening of mass spectroscopy is NEW MATTER compared to said written description as filed. Applicants argue that a specie can provide written description of a genus, a person skilled in the art would recognize that at the time of filing the inventors appreciated that their invention was not limited to one type of mass spectrometry, and that the rejection has not set forth that there are any differences in the application of different types of mass spectrometry. In response the written description requirement of 35 U.S.C. § 112, first paragraph, is directed to what is "written" as filed and does not include recognition by

inventors of broader invention practice than what was filed, a genus description when only one specie disclosed as filed, nor that differences in mass spectrometry may or may not exist. Applicants' arguments are non-persuasive regarding this rejection because they are directed to invention practice beyond what was written as filed and therefore subject to this NEW MATTER rejection as exceeding the "written" basis as filed for embodiments of the instant invention. This rejection basis is maintained from the previous office action, mailed 7/16/02.

No claim is allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application contains claims 29 and 30 drawn to an invention non-elected with traverse in Paper No. 8, filed 1/13/00. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action

(37 C.F.R. § 1.144) M.P.E.P. § 821.01.

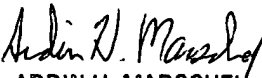
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 20, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER